

1-1-1995

Fetal Tissue Transplantation: An Ethical Approach to Proposed Regulatory Control

Lisa Melanson

Follow this and additional works at: <https://digitalcommons.schulichlaw.dal.ca/djls>



This work is licensed under a [Creative Commons Attribution-Noncommercial-No Derivative Works 3.0 License](#).

Recommended Citation

Lisa Melanson, "Fetal Tissue Transplantation: An Ethical Approach to Proposed Regulatory Control" (1995) 4 Dal J Leg Stud 73.

This Article is brought to you for free and open access by the Journals at Schulich Law Scholars. It has been accepted for inclusion in Dalhousie Journal of Legal Studies by an authorized editor of Schulich Law Scholars. For more information, please contact hannah.steeves@dal.ca.

FETAL TISSUE TRANSPLANTATION: AN ETHICAL APPROACH TO PROPOSED REGULATORY CONTROL

LISA MELANSON[†]

Fetal tissue transplantation is garnering wide-spread attention as an effective treatment for debilitating illnesses like Parkinson's disease. At present, however, the unique ethical concerns raised by a consideration of this medical procedure have not been fully addressed in a comprehensive regulatory regime. As a result, the rights of all parties to the transplantation procedure—the pregnant woman, the aborted fetus, and the recipient of the fetal tissue—have, thus far, been inadequately protected. It is therefore imperative that controls be put in place to regulate the procurement and use of fetal tissue in a manner which is particularly sensitive to the ethical issues associated with fetal tissue transplantation. A proposed statute which establishes strict requirements for consent and anonymity would largely eliminate the risks inherent in the transplantation procedure, while ensuring that the benefits of the procedure remain available to those patients awaiting fetal tissue transplants.

La greffe des tissus des fœtus comme traitement pour des maladies débilitantes attire beaucoup d'attention. Cependant, les problèmes moraux exceptionnels posés par la considération de ce procédé médical n'ont pas jusqu'ici été adressés dans un régime régulateur compréhensif. Par conséquent, les droits de tous les intéressés—la femme enceinte, le fœtus avorté, et la personne qui reçoit les tissus—ont été mal protégés jusqu'ici. Il faut donc que des contrôles soient mises en place pour réglementer l'emploi et l'acquisition des tissus des fœtus qui répondent aux questions morales posées par le procédé. Une loi proposée qui établit des exigences strictes concernant le consentement et l'anonymat éliminerait considérablement les risques du procédé, tout en assurant que les avantages du procédé restent disponibles aux malades qui attendent la greffe des tissus d'un fœtus.

[†] B.Sc. (Dalhousie), LL.B. anticipated 1995 (Dalhousie). The author wishes to thank Heather Sanford for her helpful suggestions.

In the treatment of the sick person, the doctor must be free to use a new diagnostic and therapeutic measure, if in his or her judgment it offers hope of saving life, reestablishing health or alleviating suffering.

The Declaration of Helsinki

I will maintain the utmost respect for human life from the time of conception; even under threat, I will not use my medical knowledge contrary to the laws of humanity.

The Declaration of Geneva

The transplantation of fetal tissue into adult recipients is an intensely-debated medical procedure which is garnering increased attention. Although this procedure is currently being employed in a number of institutions world-wide, it raises serious ethical and legal concerns which have not yet been fully addressed. In particular, the paucity of legislation and jurisprudence relating to fetal tissue procurement and use has created a rather urgent need for law-makers to develop measures to regulate this burgeoning area of medical law. Consequently, in this paper, I will propose a legislative model for regulatory control of fetal tissue transplantation in Canada.

In general, when our law-makers determine that a particular aspect of society requires regulation, there are numerous approaches which they may take in order to delineate legislation which will provide the requisite control. For example, legislative bodies may take an economic approach in drafting enactments, so as to promote certain economic interests, or to implement the government's economic policies. Alternatively, legislative drafters may pursue a more human rights-oriented approach, in an attempt to design legislation which will protect the rights of all members of the public. It is also possible, however, for law-makers to adopt an ethical stance to a particular matter requiring regulatory intervention, thereby transposing into explicit legislative terms the dominant ethical or moral view of the subject matter which society is currently promulgating.

The subject matter of fetal tissue transplantation entails a juxtaposition of both legal and medical issues which warrant consideration in an ethical context. Social and moral attitudes toward invasive

medical procedures and the sanctity of human life must inevitably be considered in a discussion of fetal tissue transplantation. Furthermore, individuals' deeply-rooted religious and philosophical views of the status of the fetus are, of necessity, brought to the fore when considering the use of fetal tissue for transplantation purposes.

Due to the contentious nature of fetal tissue transplantation, it is likely that any relevant legislation would be designed to address the unique ethical and moral problems raised by this procedure. Hence, it would be most appropriate if the formulators of legislation directed at regulating fetal tissue transplantation were to take an ethical approach to the task. It is only through an examination and analysis of the particular ethical issues raised by a discussion of fetal tissue transplantation that legislators can ensure that the interests of all involved in the procedure will be protected, and that the inherent risks to the participants will be lessened or eliminated.

Accordingly, this paper seeks to analyze the significant ethical and moral issues which must be addressed when considering the subject of fetal tissue transplantation. Taking this ethical approach to the matter, a legislative model for regulatory control of fetal tissue transplantation will be proposed, which will reflect and, hopefully, alleviate the distinctive ethical concerns raised by this promising medical procedure.

I. MEDICAL USES OF HUMAN FETAL TISSUE

1. Applications of Fetal Tissue Transplantation

The use of human fetal tissue in transplantation therapy is not a new practice. As early as 1928, for example, attempts were made to transplant fetal pancreatic cells into patients suffering from diabetes.¹ Fetal thymus transplantation to treat DiGeorge's syndrome is another primary application of fetal tissue transplantation which is currently in use.²

¹ M. C. Coutts, "Fetal Tissue Research" Scope Note 21, Georgetown University (Washington, D.C.: National Reference Center for Bioethics Literature, Kennedy Institute of Ethics, 1993) at 1.

² M. A. Mullen, "The Use of Human Embryos and Fetal Tissues: A Research Architecture" in *Royal Commission on New Reproductive Technologies, Background and Current Practice of Fetal Tissue and Embryo Research in Canada*, vol. 15 (Minister of Supply and Services Ottawa: Canada, 1993) at 16.

In addition to its initial historical contributions, there has recently been rapid growth in the potential uses of fetal tissue transplantation. New, secondary uses include the clinical treatment of such diseases as type-I diabetes (diabetes mellitus), and Parkinson's disease.³ Some potential tertiary applications of fetal tissue transplantation include its use in treating leukemia, aplastic anemia, inherited metabolic storage disorders such as Tay-Sachs disease, and AIDS.⁴

Parkinson's disease is one of the most common neurologic disorders affecting people over fifty-five years of age. It results from the degeneration of dopamine-secreting cells in a portion of the mid-brain. The cause of this progressive and irreversible condition is unknown, and there are no treatments available that can stop or reverse the degeneration of cells.⁵ Transplantation using adult tissue is not possible, because the process of transplantation damages mature brain cells, which do not regenerate and cannot be kept alive.⁶ However, experiments have demonstrated that transplantation of an appropriate suspension of fetal brain tissue into the brains of Parkinson's patients can, in certain circumstances, restore normal brain function.⁷ It is believed that the dopamine-secreting fetal cells, which are selected from the brains of aborted fetuses, continue to produce dopamine in the brains of transplant recipients. The fetal cells may also encourage the recipient's own cells to produce dopamine.⁸

The use of fetal cells in Parkinson's patients is not yet a proven treatment,⁹ and very limited human studies are being conducted. As of 1993, the Victoria General Hospital in Halifax, Nova Scotia, was the only institution in Canada carrying out research using fetal tissue transplantation in human subjects.¹⁰ The procedure followed by the

³ *Ibid.*

⁴ *Ibid.* at 18–21. The final application which Mullen notes is plastic surgery/cosmetic treatment. This, however, is clearly beyond the ethical and justifiable scale of uses, in most cases.

⁵ M. K. Elsom, "Fetal Tissue Transplants" (1992) 88 Can. Nurse 31 at 31.

⁶ G. Morgan, "The Regulation of Fetal Tissue Transplantation" (1991) 14 U.N.S.W. L. J. 283 at 285–86.

⁷ M. Elsom, *supra* note 5 at 31.

⁸ D. Jones, "Halifax Hospital First in Canada to Proceed with Controversial Fetal-Tissue Transplant" (1992) 146:3 CMAJ 389 at 390.

⁹ *Supra* note 2 at 15.

¹⁰ Royal Commission on New Reproductive Technologies, *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies* (Ottawa: Minister of Government Services, 1993) at 977.

Victoria General Hospital in instituting its fetal tissue research program will be a point of reference later in this paper when the regulation and control of fetal tissue procurement is discussed.

The usual source of human fetal tissue for transplantation is first-trimester abortions.¹¹ Fetal tissue is currently procured for research and therapeutic use from approximately one percent of all therapeutic abortions performed in Canadian hospitals, including the Victoria General Hospital.¹² Although the figures seem to suggest that the tissue available from therapeutic abortions would be more than sufficient to accommodate the need for tissue for transplantation in the foreseeable future,¹³ this assertion has been contested. Douglas Martin, for instance, states:

Given approximately 90,000 first-trimester abortions in Canada annually, potentially there is enough usable aborted foetal tissue to support even an enthusiastic nationwide research undertaking. However, if FTT [fetal tissue transplantation] evolves into treatment, the number of Parkinson's disease and diabetes patients alone, for which FTT may be a therapeutic option, creates a tissue supply shortage.¹⁴

Consequently, we could reach a point in the future when our demand for fetuses from therapeutic abortions might exceed the supply.

2. Narrowing the Scope

Fetal tissue transplantation represents a broad topic encompassing a multitude of sub-issues. This paper focuses solely on the issues surrounding transplantation of tissue removed from dead fetuses (i.e., dead *ex utero* fetuses that have already been aborted by way of therapeutic abortion).¹⁵ I will also assume the existence of a supply of fetal tissue from therapeutic abortions sufficient to meet any demand for fetal tissue. Finally, although fetal tissue transplantation is employed to improve the circumstances of certain patients (i.e., as a type of

¹¹ *Supra* note 2 at 7.

¹² *Supra* note 10 at 986.

¹³ *Ibid.* at 989.

¹⁴ D. K. Martin, "Foetal Tissue Transplantation Research: A Canadian Policy Analysis" (1992) 13 Health L. Can. 132 at 135.

¹⁵ Fetal tissue cells can remain in a suitable form for transplantation for up to several hours after an abortion, even though the fetus itself is incapable of maintaining a heart beat and respiration. *Supra* note 10 at 971.

treatment), it is not yet well-established in the health care system (and is therefore still viewed as an experimental procedure). Hence, I will not make any distinction between research and treatment in the following discussion of fetal tissue transplantation.

II. ETHICAL ANALYSIS

The ethics of fetal tissue transplantation can be considered from a number of different points of view. In the following analysis, the perceived risks and benefits of fetal tissue transplantation will be assessed, and the status of the fetus will be reviewed. These ethical issues will then be evaluated in terms of the general principles of biomedical ethics. The conclusions reached in the ethical analysis can then form a theoretical framework around which proposed future legislation can be designed. The focus of the present analysis will be on the ethics of fetal tissue transplantation; therefore, the complex issues relating to abortion will not be dealt with, except insofar as they are relevant to the discussion.

1. Detrimental Aspects of Fetal Tissue Transplantation

i. Increase in the Abortion Rate

Many opponents of fetal tissue transplantation believe that induced abortion is morally wrong, and that the use of fetal tissue from therapeutic abortions legitimizes abortion.¹⁶ Others contend that fetal tissue transplantation will encourage abortions which would not otherwise occur.¹⁷ They envisage a scenario where a pregnant woman, who is undecided about whether or not to have an abortion, proceeds with the abortion after learning that she can help another person by donating the resulting fetal tissue. Consequently, it is feared that the development of successful fetal tissue transplantation therapies might indirectly lead to an increase in the abortion rate.

ii. Commodification and Commercialization of Fetuses

Plaintiff has asked us to recognize and enforce a right to sell one's own body tissue *for profit*. He entreats us to regard the human vessel—the single most venerated and protected subject

¹⁶ *Supra* note 1 at 5.

¹⁷ J. A. Robertson, "Rights, Symbolism, and Public Policy in Fetal Tissue Transplants" (1988) 18 *Hast. Cent. Rpt.* 5 at 6.

in any civilized society—as equal with the basest commercial commodity. He urges us to commingle the sacred with the profane. He asks much.¹⁸

In addition to ethical concerns about fetal and maternal welfare, opponents of fetal tissue transplants have raised the spectre of a commercial market in fetal tissue.¹⁹ A market in fetal tissue is problematic for at least three reasons. Firstly, allowing or encouraging the purchase of fetal tissue risks exploiting women and their reproductive capacities, especially since it is likely that the main suppliers of such tissue would be those who are poor.²⁰ Secondly, there is some concern that the existence of a market in fetal tissue, and non-altruistic financial motives, would provide an incentive to abort.²¹ Thirdly, paying women to abort, or to donate once they abort, along with the commercial buying and selling of fetal tissue and products made from fetal tissue, is generally perceived as damaging to human dignity.²² As Christine Overall argues, the immorality of commercial exchanges in human fetal tissue stems from the fact that a person is not the sort of thing which may be bought or sold. Even if the fetus is not a person, it may eventually become one; therefore, it is not something which ought to be bargained with.²³

iii. Coercion of Women

There is some worry that pregnant women may be pressured into having an abortion by a physician, researcher, or sick family member—through coercion or undue influence—in order to donate fetal tissue for transplantation.²⁴ It is also feared that a woman could first be coerced into becoming pregnant, and then coaxed into having an abortion to provide fetal cells for transplantation.

¹⁸ *Per Arabian, J. in Moore v. Regents of the University of California*, 271 Cal. Rptr. 146 (Cal. S.C. 1990) at 164.

¹⁹ *Supra* note 5 at 31.

²⁰ *Supra* note 17 at 10.

²¹ A. Fine, "The Ethics of Fetal Tissue Transplants" (1988) 18 *Hast. Cent. Rpt.* 5 at 6–7.

²² *Supra* note 17 at 10.

²³ C. Overall "Pluck a Fetus from its Womb: A Critique of Current Attitudes Toward the Embryo/Fetus" (1986) 24 *U.W.O.L. Rev.* 1 at 9.

²⁴ D. Brahams, "Transplantation, the Fetus and the Law" (1988) 138 *New L.J.* 91 at 91.

iv. Unnecessary Risk to the Pregnant Woman

Although it is preferable to separate the moral issues and controversy surrounding therapeutic abortion from the use of fetal tissue for transplantation, it must be acknowledged that the type of abortion does affect the usability of the tissue in treatment. As stated by Dorothy Vawter *et al.*:

Abortion and procurement procedures are sometimes altered to increase the chances of obtaining certain types of fetal tissue. It is unknown whether such modifications increase the risks of harm, discomfort, or inconvenience to women, or increase the chance that tissue is removed from living fetuses. It is also unknown whether women are informed of the modifications that will be made if they consent to donate fetal tissue.²⁵

Thus, there is a fear that procurement of fetal tissue in a medically-useful form could expose the pregnant woman to unnecessary risk.²⁶ Presently, suction curettage is the safest available procedure for terminating pregnancies at the stage of fetal development optimal for tissue procurement. Since the supply of fetal tissue by this procedure currently exceeds the anticipated demand, there is no justification for exposing the mother to riskier procedures in order to obtain usable fetal tissue.²⁷ However, in the future, for certain treatments, gestation may need to be prolonged, and the method of abortion may therefore need to be altered to increase the chances of therapeutic success for the recipient.²⁸

v. Unacceptable Risk to the Recipient of the Tissue

It must also be recognized that fetal tissue transplantation is, at present, an experimental procedure; therefore, an unsatisfactory outcome is possible. The grafts may be without effect, or their excessive growth could further compromise the recipient's own tissue function, thereby exacerbating symptoms. Infection or inflammation as a result of the surgery could also be fatal.²⁹ Any potential benefits of fetal

²⁵ D. E. Vawter *et al.*, *The Use of Human Fetal Tissue: Scientific, Ethical, and Policy Concerns* (Minneapolis: University of Minnesota, 1990) at 7.

²⁶ *Supra* note 21 at 5.

²⁷ *Ibid.* at 7.

²⁸ M. B. Mahowald, J. Silver & R. A. Ratcheson, "The Ethical Options in Transplanting Fetal Tissue" (1987) 17 *Hast. Cent. Rpt.* 9 at 13.

²⁹ *Supra* note 21 at 8.

tissue transplantation must therefore be weighed against the possibility that the treatment might not even work.

vi. Brutalization of Medical Researchers

Some authors see the use of aborted fetal tissue as the first step down a slippery slope leading to the creation of researchers without moral integrity and without concern for the dignity of the research subject or the dead fetus. In particular, Dr. Alan Fine, a key researcher into fetal tissue transplants at the Victoria General Hospital, is very concerned with the empirical possibility that these procedures may brutalize those parties involved in carrying out the transplantations.³⁰ There is further concern that the transplantation process may eventually expand to include the transplantation of tissue from living, though nonviable, fetuses, or the transplantation of whole fetal brains.³¹

2. Beneficial Aspects of Fetal Tissue Transplantation

i. Therapeutic Use to Alleviate Human Suffering

There are undeniable benefits which can be reaped from the use of fetal tissue in transplantation research and treatment. Proponents especially emphasize the long-awaited benefits for people suffering from incurable illnesses, such as Parkinson's disease.³² Three main characteristics of this disease support research into fetal tissue transplantation: the poor prognosis of patients under alternative treatments; the great clinical promise shown by research studies into fetal tissue transplantation;³³ and the current lack of a satisfactory cure.³⁴

ii. Potential Risks Not Substantiated

The feared impact of fetal tissue transplantation on abortion practices and attitudes is actually highly speculative.³⁵ The main motivation for

³⁰ *Ibid.* at 6.

³¹ *Supra* note 28 at 14.

³² *Supra* note 1 at 5.

³³ *Supra* note 5 at 31.

³⁴ *Supra* note 21 at 5.

³⁵ In fact, any risk of an increased abortion rate, commercialization of fetal tissue, or coercion of women has been unsubstantiated thus far in the Victoria General Hospital transplant program: Dr. J. V. Jones (former Chair, Victoria General Hospital Research Review Committee, 22 April 1994) [personal communication].

abortion is the desire to avoid an unwanted pregnancy. The fact that fetal remains may be donated for transplant will continue to be of little significance in the total spectrum of factors which lead a pregnant woman to have an abortion. Having decided to abort, a woman may feel better if she then donates the fetal remains; yet, this does not prove that tissue donation will lead to a termination decision which would not otherwise have occurred.³⁶ Furthermore, if a woman who aborts chooses to donate the fetal remains in the hope that some good might result from the abortion, then paying her to donate is unnecessary.³⁷ In fact, assuming that the supply of fetal tissue can readily meet the demand, it is not very likely that pregnant women will be asked to abort their fetuses for payment. Accordingly, the development of a market in fetal tissue, although serious, is only a mere possibility. Concerns regarding coercion of pregnant women are also less likely to materialize in situations where the supply of appropriate fetal tissue is sufficient to meet the demand. In fact, given the present availability of fetal tissue obtainable from therapeutic abortions, it is unlikely that there will be increased pressure for women to donate fetal tissue for transplantation.³⁸ Finally, there is no indication thus far that fetal tissue transplantation desensitizes scientists, physicians, or nurses to the value of life.³⁹

It appears, then, that the potential risks often associated with fetal tissue transplantation have not been substantiated, either in practice or in theory. Furthermore, fetal tissue transplantations which have been carried out to date have produced results which indicate that this procedure may prove to be very beneficial in the treatment of some debilitating illnesses, such as Parkinson's disease. Hence, in light of the proven benefits produced by fetal tissue transplantation, speculations on the presently unsubstantiated risks of this procedure do not represent a sufficient justification for an outright ban on fetal tissue transplantation.

3. Status of the Fetus in Relation to the Mother

Although the focus of this paper is not directed at the ethical implications of abortion, one aspect of the abortion debate is necessarily relevant to the present discussion: the status of the fetus. It is essential

³⁶ *Supra* note 17 at 6–7.

³⁷ *Ibid.* at 10.

³⁸ *Supra* note 10 at 999.

³⁹ *Supra* note 21 at 6.

to clarify this issue, as it will ultimately determine, in most cases, one's feelings toward the ethical and legal issues relating to fetal tissue transplantation. However, as the scope of this paper extends only to those ethical issues relating to the use of fetal tissue obtained from dead fetuses which have been therapeutically aborted, those aspects of the abortion debate which centre on the status of the *in utero* fetus will be of only marginal relevance to the present discussion.⁴⁰

Currently, in Canada, the status of the fetus and the mother is unsettled.⁴¹ Recent case law indicates, however, that a fetus is not a person until it issues from the mother.⁴² There are three main ethical frameworks which specifically consider the status of the dead fetus. Each of these frameworks is relevant to an analysis of the ethics of fetal tissue transplantation.⁴³

i. The Dead Fetus as Human Research Subject

The first ethical framework views the dead *ex utero* fetus as a human research subject in its own right. As a result, the dead fetus is accorded its own status, independent from its mother; therefore, it deserves to be treated with a degree of dignity comparable to that shown to all other deceased human research subjects. Most opponents of abortion similarly consider the *in utero* or *ex utero* fetus as having a status completely independent from its mother. According to this conservative perspective, the fetus is in most, if not all, fundamental respects like any other human. Even though actual personhood is not fixed until birth, the humanity of the fetus, according to this point of view, should not be overlooked.⁴⁴

It is not surprising, then, that the ethical framework which views the dead fetus as a human research subject is often supported by those who oppose abortion. Both perspectives view the fetus as an entity

⁴⁰ For a consideration of the status of the *in utero* fetus in Canada, specifically in relation to the abortion issue, see M. L. McConnell, "Sui Generis: The Legal Nature of the Foetus in Canada" (1991) 70 Can. Bar Rev. 548; S. A. Tateishi, "Apprehending the Fetus *En Ventre Sa Mere*: A Study of Judicial Sleight of Hand" (1989) 53 Sask. L. Rev. 113; and C. Tolton, "Medicolegal Implications of Constitutional Status for the Unborn: 'Ambulatory Chalice' or 'Priorities and Aspirations'" (1988-89) 47 U. T. Fac. L. Rev. 1.

⁴¹ *Ibid.*

⁴² See, e.g., *R. v. Sullivan and Lemay* (1991), 122 N.R. 166 (S.C.C.).

⁴³ *Supra* note 25 at 211.

⁴⁴ C. M. Meechan, "Fetal Experimentation: Protocols, Propriety and Parameters" (1985-86) 11 Queen's L. J. 166 at 174.

independent from its mother. Hence, both positions advocate, on behalf of the fetus, that the dignity of the dead fetus should be accorded the same protection as that granted to other independent human research subjects.

A positive feature of this first ethical framework is that it requires special review by an interdisciplinary group of persons interested in minimizing risks and obtaining informed consent.⁴⁵ This protocol is necessary if the dead fetus is to receive treatment comparable to that provided to other human research subjects. A proxy decision-maker must consent, on behalf of the fetus, to the procurement of fetal tissue for transplantation. The proxy is required to base his or her decision either on the basis of what the dead fetus would have wanted, or on some view of what is in the dead fetus' best interest.⁴⁶ It is extremely difficult to see how any proxy decision-maker could rely on either of these ethical standards in forming his or her decision. Furthermore, proponents of this ethical framework hold that parents, who normally serve as proxy decision-makers for fetuses involved in research, abdicate their right to make a decision on behalf of the fetus once they decide to abort. For example, Kathleen Nolan argues:

It would in general seem desirable to disqualify anyone having agency in another's death from then serving as a proxy for the purpose of making a donation. To participate in another's death is ultimately to objectify that other, to use the other for purposes not of his or her own. Thus, even if one believes elective abortion can be ethically justified (in general, or in specific cases), maternal consent—or indeed, societal consent—to donation still generates misgivings.⁴⁷

Proponents of this view therefore conclude that all fetal tissue transplantation should be prohibited, as it is not possible to find anyone who can formulate a proper decision on behalf of the dead fetus, and who can rightfully serve as proxy decision-maker.

Critics of this framework maintain that the ethics of conducting research on a living fetus are not the same as the ethics of conducting research involving a dead fetus or its tissue. Never having walked, or talked, or interacted with others as an individual, an aborted fetus is

⁴⁵ *Supra* note 25 at 227.

⁴⁶ *Ibid.* at 213.

⁴⁷ K. Nolan, "Genug ist Genug: A Fetus is Not a Kidney" (1988) 18:6 *Hast. Cent. Rpt.* 13 at 14.

not identical in status to a cadaver.⁴⁸ It is argued that dead fetuses cannot be physically or emotionally harmed, and cannot be wronged by being the subject of research. However, the pregnant woman undergoing an abortion, who subsequently donates the resulting fetal tissue, could be potentially subjected to both physical and emotional harm. Hence, the woman from whom the fetal tissue is removed should be viewed as the human research subject in need of protection, and not the dead fetus.⁴⁹ I concur with these critics that the possibility that the pregnant woman might suffer actual harm requires that we elevate her status above that of the dead, aborted fetus which *cannot* be physically or emotionally harmed.

Critics also see serious flaws in the argument that a woman who elects to have an abortion should be disqualified from making a surrogate decision on behalf of the fetus whose life she has terminated. Firstly, deceased persons or fetuses no longer have interests to be protected, as the notion of proxy implies. Secondly, it is contended (and rightfully so) that it is a mistake to assume that a woman has no interest in what happens to the fetus which she chooses to abort.⁵⁰ Each woman has her own compelling reasons for choosing to terminate her pregnancy, and she may care deeply about whether fetal remains are contributed to research or therapy to help others. For instance, a pregnant woman may choose to discontinue her pregnancy because it poses a serious threat to her life or health. The circumstances of each woman are different, and we should not shroud the decision with blanket assumptions which might be totally inaccurate and misdirected.

ii. The Dead Fetus as a Cadaveric Organ Donor

There is a well-established legal and ethical tradition which provides each person with the autonomous right to control the disposition of his or her bodily remains after death. This right is formalized in our provincial human tissue gift legislation.⁵¹ Such legislation requires that consent be obtained prior to any use of the body or its parts in medical research or therapy. Such legislation also generally allows for

⁴⁸ J. M. Hillebrecht, "Regulating the Clinical Uses of Fetal Tissue" (1989) 10 J. Leg. Med. 269 at 283.

⁴⁹ *Supra* note 25 at 213–14.

⁵⁰ *Supra* note 17 at 9.

⁵¹ See, for example, *Human Tissue Gift Act*, R.S.N.S. 1989, c. 215, as am. S.N.S. 1991, c. 13.

the disposition of remains by family members when there has been no direct indication of the deceased's opposition to such a donation.

Those who view the dead fetus as a cadaveric organ donor argue that fetal tissue may be dealt with according to such human tissue gift legislation. Adopting this framework would mean that either parent of the dead fetus would have decision-making power regarding donation; the decision whether or not to donate fetal tissue would not be the prerogative of the woman alone.⁵² However, those who reject this view of the status of the dead fetus argue that the mother is the subject whose rights need to be protected; hence, the father or sperm source should not have decision-making power, or indeed any role, in the consent process relating to the procurement of tissue from an aborted fetus. There is also a concern that a woman could feel coerced, or have a new incentive, to abort a fetus she would not otherwise abort if the father retained his decision-making power.⁵³

iii. The Dead Fetus as a Tissue Specimen of the Mother

At the liberal end of the ethical spectrum lies the viewpoint which regards the dead fetus as a tissue specimen from the mother.⁵⁴ Proponents of this view contend that the issue of consent is paramount in the procurement of fetal tissue for transplantation. It is the consent of the mother on her own behalf, and not as proxy for the fetus, which must be obtained before the fetal tissue may be procured for use in transplantation. The father does not retain any right to veto the procurement of the fetal tissue.⁵⁵

In addition, it is customary in medical practice for fetal remains, post-abortion, to have the same moral status as that accorded any other specimen removed from a woman during surgery.⁵⁶ This lends support to proponents of this ethical framework who view the dead fetus as a tissue specimen of the mother. The existence of potential harm to the pregnant woman during the procurement process, and the absence of potential harm to the dead fetus, also support this ethical viewpoint.

Opponents of this framework object to viewing the fetus as a tissue specimen of the mother. They assert that the fetus is not merely a

⁵² *Supra* note 25 at 216–17.

⁵³ *Ibid.* at 228.

⁵⁴ *Supra* note 44 at 174.

⁵⁵ *Supra* note 25 at 224.

⁵⁶ *Ibid.*

mass of cells which form a part of a pregnant woman's body, but is a separate human being with its own gender and genetic identity.⁵⁷ Kathleen Nolan, for example, states that "[t]reating fetal cadavers under a model that approximates routine salvage cannot help but depreciate and objectify them";⁵⁸ a "fetus isn't a kidney, even when we act as if it is" ⁵⁹

Opponents also point to the decision in the case of *Moore v. Regents of the University of California*⁶⁰ in support of their position. In that case, physicians used Moore's spleen, which had been surgically removed, to develop a profitable cell line. The physicians did not inform Moore that they intended to use the spleen cells for this purpose. The Supreme Court of California found that the physicians had breached their fiduciary duty in neglecting to disclose personal interests unrelated to the patient's health, and in failing to obtain Moore's informed consent.

Although the findings in *Moore* are not binding on Canadian courts, the reasoning in this case does suggest that legal thinking in matters relating to tissue removal may be changing. In particular, the *Moore* decision has arguably weakened the common law presumption that when a patient enters a hospital, he or she implicitly abandons to science any tissues removed during surgery.⁶¹

In the present context, the *Moore* case suggests that, at a minimum, the potential to treat specimens as property might require researchers to seek explicit consent from the mother, should they desire to use fetal tissue for transplantation. At a maximum, researchers may have to share with the mother any profits made from the manufacture of products using fetal cells.⁶² Consequently, there is a fear that if a dead fetus is viewed as being a tissue specimen, or property of the mother, then women could be provided with new financial inducements to abort, or to become pregnant for the purpose of aborting

⁵⁷ *Ibid.* at 226.

⁵⁸ *Supra* note 47 at 17.

⁵⁹ *Ibid.* at 19.

⁶⁰ 271 Cal. Rptr. 146 (Cal. C.A. 1990).

⁶¹ *Supra* note 10 at 991.

⁶² For further implications of the *Moore* decision, see B. Hoffmaster, "Between the Sacred and the Profane: Bodies, Property, and Patents in the *Moore* Case" (1992-93) 7 I. P. J. 115, and R. W. Marusyk & M. S. Swain, "A Question of Property Rights in the Human Body" (1989) 21 Ottawa L. Rev. 351.

the fetus and donating the resulting tissue.⁶³ Nevertheless, it is this framework which has dominated fetal tissue procurement.⁶⁴

As indicated earlier, the pregnant woman, and not the dead fetus, may potentially be harmed, either physically or emotionally, by the procurement of fetal tissue. As well, the pregnant woman, and not the dead fetus, is accorded certain rights at law. Each of these views is consistent with the third ethical framework, which requires that the mother's consent be obtained before fetal tissue is procured, and which denies the dead fetus any moral or legal status above that of all other tissue specimens removed from the mother. Thus, I think it is appropriate that the tissue from a *dead, aborted fetus* be viewed as a tissue specimen from the mother's body.

4. Principles of Biomedical Ethics

In their text, *Principles of Biomedical Ethics*,⁶⁵ Beauchamp and Childress adopt a deontological perspective of biomedical ethics, and set out four primary rules according to which acts or decisions in the biomedical field may be judged. These four principles are: autonomy, nonmaleficence, beneficence, and justice. The preceding ethical analysis will now be considered in light of these four principles.

Autonomy is generally viewed as the primary principle which cannot easily be overridden by the other three principles. Unlike many contentious issues, however, the principles of beneficence and autonomy are not directly in conflict here, because it is not universally-accepted that fetal tissue transplantation is a beneficial and socially acceptable form of treatment. As well, the benefits of such treatment do not directly accrue to the parties who might be required to consent to the donation of fetal tissue—the mother and/or the fetus. Hence, the benefits and risks of the procedure are initially weighed in order to determine if fetal tissue transplantation is inherently beneficial. Concluding that such transplantation should occur, the principle of autonomy (and its requisite consent) is discussed, followed by a review of relevant justice issues.

⁶³ Until either legislators or courts address issues such as those in *Moore*, the Canadian position in this area will remain unclear: Marusyk & Swain, *supra* note 62.

⁶⁴ *Supra* note 25 at 228.

⁶⁵ T. L. Beauchamp & J. F. Childress, *Principles of Biomedical Ethics*, 3d ed. (New York: Oxford University Press, 1989).

i. Beneficence

The principle of beneficence reflects an obligation to actively confer benefits, and to balance the possible benefits against the possible risks of a procedure.⁶⁶ The main positive aspect of fetal tissue transplantation—the treatment of persons with debilitating and incurable diseases—weighs heavily in favour of such a medical procedure. The treatment does appear to be successful in many instances, and, thus far, there do not appear to be any serious side effects. Furthermore, there are currently no other alternatives to the treatment of serious neurologic disorders like Parkinson's disease.⁶⁷ The lack of other treatment options therefore increases the intrinsic beneficial value of fetal tissue transplantation.

It is evident, then, that fetal tissue transplantation can make a difference in certain patients, especially those with Parkinson's disease. Thus, unless the risks dramatically outweigh the benefits of this treatment, fetal tissue transplantation should be pursued. The possibility of benefit to persons suffering from disease suggests that there is an ethical obligation to proceed with such treatment, providing that it can be done without harm to others.

ii. Nonmaleficence

The principle of nonmaleficence reflects an obligation of non-infliction of harm.⁶⁸ In terms of fetal tissue transplantations, there are a number of parties who might be harmed by this medical procedure, including future fetuses, the pregnant woman, the recipient of the tissue, and researchers. It is essential that researchers and physicians ensure that they are not inflicting unnecessary harm on any of these parties before the procedure should be promoted. The fetus whose tissues are actually procured cannot be harmed in the context of this discussion, as I am focusing solely on the use of tissue taken from a dead fetus which has already been aborted.⁶⁹

It is conceivable that harm to future fetuses might arise under the guise of an increase in the abortion rate, possibly coupled with the

⁶⁶ *Ibid.* at 195.

⁶⁷ *Supra* note 21 at 7.

⁶⁸ *Supra* note 65 at 120.

⁶⁹ Some, of course, would argue that the dignity of the dead fetus, as a potential human being, may still be harmed by tissue transplantation. However, as I have adopted the position that the status of the dead fetus is equivalent to that of the mother's tissue specimens, the conservative view of the dead fetus is not persuasive.

commodification and commercialization of fetal tissue, or coercion of an undecided mother into having an abortion. However, it has been noted that these fears are perhaps exaggerated. Furthermore, it is quite possible to mitigate any of these nebulous risks through proper legislation or regulation. For instance, a complete prohibition on the sale of fetal tissues and products made from fetal tissue, and on the payment to women from whom the tissue is obtained, can ensure that commodification and commercialization of fetal tissue do not occur.⁷⁰ It has also been suggested that any discussion of the use of fetal tissue for research should be deferred until after the woman gives informed consent to the abortion.⁷¹ This can help prevent coercion of the pregnant woman, and ensure that tissue donation does not lead to a termination decision which would not otherwise have occurred. Coercion can also be diminished through a prohibition on designation of the fetal tissue recipient.⁷²

Similarly, any physical risk to the pregnant woman or to the eventual recipient of the fetal tissue can be lessened or alleviated by requiring voluntary, informed consent from both parties.⁷³ If the researchers and physicians fully disclose to both the pregnant woman and the tissue recipient the potential risks of the procedure, and allow these individuals the freedom to make their own decisions, then the voluntary choices of these autonomous patients cannot be questioned. Finally, it has been suggested that harm might come to researchers involved in fetal tissue transplants, in the form of brutalization. This, again, is a rather elusive fear, and has not yet been substantiated.⁷⁴

Taken as a whole, then, the obligation upon physicians and researchers not to inflict harm is trumped by the benefit conferred upon seriously ill patients by the process of fetal tissue transplantation. The existence of alternatives or safeguards to alleviate the risks, and the current absence of alternative treatments to assist sufferers of chronic disorders, justify the introduction of fetal tissue transplantation into the Canadian health care system. It must now be determined what consent, if any, is required before fetal tissue may be procured, and from whom consent should be obtained.

⁷⁰ *Supra* note 10 at 1002.

⁷¹ *Ibid.* at 997.

⁷² *Ibid.* at 999.

⁷³ *Supra* note 21 at 7–8.

⁷⁴ *Supra* note 21 at 6.

iii. Autonomy

According to Beauchamp and Childress, the principle of autonomy encompasses a number of requirements, including the right to refuse treatment, the right to consent to treatment, the right to have full information so that autonomous decision-making can be fostered, and avoidance of coercion.⁷⁵ In the context of fetal tissue transplants, the issue of consent is most relevant. One's view of the status of the fetus ultimately dictates which party should be providing consent to the procedure, and on whose behalf the consent is given.

If the status of the fetus is equated with that of other tissues in the mother's body, it is clear that only the mother's consent is relevant to a determination of the eventual disposition of the fetal tissue. There is no decision-making role for the father within this ethical framework.⁷⁶ Furthermore, the mother is providing this consent on her own behalf; her consent is not given as a surrogate decision on behalf of the dead fetus. What degree of consent is required before fetal tissue may be procured for the purposes of transplantation?

Assuming the pregnant woman retains the right to determine whether fetal tissue is used for transplantation, the main ethical goal is to ensure that her choice about the abortion, and her decision regarding tissue donation, are both "free and informed."⁷⁷ Firstly, the woman must be fully informed of the use to which the fetal tissue may be put. Secondly, it is essential that there be a clear separation of the decision to abort and the decision to donate, so that tissue donation is not seen as a prerequisite to the performance of an abortion. This will reduce the chances that the pregnant woman will be coerced into either obtaining an abortion, or donating the resulting fetal tissue. In addition, the physician performing the abortion, and the person requesting consent to tissue donation, should not be involved in the subsequent tissue procurement and transplantation procedures, a constraint widely followed in cadaveric organ procurement.⁷⁸ This can also serve to counteract any opportunities for coercion, and thus ensure that the pregnant woman makes a fully autonomous choice.

⁷⁵ *Supra* note 65 at 73.

⁷⁶ The position of the father or sperm source *is* relevant to the decision whether or not to abort, and has formed the basis of many Supreme Court of Canada rulings on abortion: See, e.g., *Tremblay v. Daigle*, [1989] 2 S.C.R. 530.

⁷⁷ *Supra* note 17 at 9.

⁷⁸ *Supra* note 17 at 9.

If there is a clear separation between the decision to abort and the decision to donate, researchers would be unable to alter the type of abortion which a woman will undergo, as there would be no mention of the procurement of fetal tissue until after the abortion consent form has been signed. Consequently, the researchers and physicians will have to be satisfied with the gestational age of the fetuses which are produced, and the quality of the tissue provided. They will therefore be unable to request that the pregnant woman undergo a certain type of abortion procedure which might expose her to unnecessary risks. However, assuming that the supply of usable fetal tissue is adequate to meet the demand, the possibility that a woman may be asked to undergo a more dangerous type of abortion is virtually eliminated.

iv. Justice

The principle of justice is generally perceived in terms of fairness and claims of entitlement.⁷⁹ Although this paper assumes a constant supply of fetal tissue sufficient to meet the demand, problems of distributive justice, and allocation of public resources, might arise under conditions of scarcity of fetal tissue. Absent any current regulatory mandate, there is a potential for development of a demand for fetal tissue which exceeds the supply. It is therefore necessary to put into place restrictions which ensure that the health of the mother remains the paramount concern, and that scarce fetal tissue is not procured at any cost. It is also necessary to take into consideration the potential for the development of a bio-commerce in scarce fetal tissue. A fetus is, arguably, a “regenerative” tissue, as it can, in general, be created at will; thus, it is particularly suited to commodification. The principle of distributive justice requires that scarce resources be allocated to those who need these resources the most—not necessarily to those with the greatest financial means. Therefore, regulations must be put in place to prohibit both the sale of fetal tissue and products made from fetal tissue, and the payment of women in exchange for aborted fetal tissue.

Given the controversial nature of the use of aborted fetal tissue, allocation of public funds to such research is presently unlikely. Although legislators have not prohibited fetal tissue transplantation thus far, conscious ignorance is not an adequate response to the issue. Fetal tissue transplantation therapy is still a last resort for patients

⁷⁹ *Supra* note 65 at 257.

who have not responded to, or have rejected, alternative treatments. Yet, it is still a valid concern that treatments dependent on a supply of fetal tissue may become the primary method for treating a particular disease, to the exclusion of standard treatments. It is therefore essential that future legislators remain cognizant of the potential uses of fetal tissue in transplantation in order to accurately assess the allocation of public funding, and to ensure a just distribution of limited resources.

III. CURRENT AND PROPOSED REGULATORY CONTROLS

It is clear from the ethical concerns raised in the previous discussion that some standards are needed to regulate fetal tissue transplantation. The following legal analysis will initially consider what regulation currently exists. The adaptability of present regulatory controls will then be evaluated to determine if they are sufficient to deal with the ethical problems created by fetal tissue transplantation. Legislation enacted in jurisdictions other than Canada will be reviewed briefly, in order to gain some insight into the potential for legislative regulation in the area of fetal tissue transplantation. Finally, in employing and implementing the ethical requirements set out in the ethical analysis, the type of law needed to regulate fetal tissue transplantation will be proposed.

1. Current Regulation of Fetal Tissue Transplantation

The procurement and use of fetal tissue is not currently regulated in a comprehensive manner by any level of government in Canada. Thus, guidance must be taken from existing provincial human tissue gift legislation, provincial health legislation regulating the disposal of abandoned tissues, national guidelines for research involving human subjects, and internal policy guidelines established in institutions where abortions and/or procurement of fetal tissue take place.

i. Human Tissue Gift Legislation

Currently, human organs and tissues are acquired and utilized according to provincial legislation, such as the Nova Scotia *Human*

Tissue Gift Act.⁸⁰ Statutes of this kind attempt to ensure that existing rights are recognized; appropriate consent is obtained; the sale of human tissues is prohibited; and anonymous, equitable distribution occurs. Such legislation does not specifically include fetal tissue. However, in the Manitoba and Prince Edward Island legislation, fetuses are specifically excluded from the definition of "tissue."⁸¹

ii. Provincial Health Legislation

Regulations enacted under existing Nova Scotia and New Brunswick hospital legislation do, however, refer to tissues removed from a patient during the curettage procedure.⁸² These regulations generally provide for the disposal of fetal tissue in a manner similar to that used for other abandoned tissues. Nevertheless, neither regulation considers the actual procurement and use of fetal tissue for transplantation purposes. Hence, there is a gap in the legislation relating to this area.

iii. National Research Guidelines

The Medical Research Council of Canada (MRC) is a pseudo-governmental agency which regulates funding for medical research. This organization is viewed as a "special interest group," and is comprised of basic scientists and physicians who have professional interests in medical research.⁸³ In 1987, the MRC issued a set of guidelines that apply to the conduct of medical research. Compliance with these guidelines is necessary where the research is funded by the federal government.⁸⁴

Under the heading of "Research on Fetuses," the MRC *Guidelines* state:

Separated tissue and placental material may be regarded as routine pathological tissue, and may be used in research, subject to the permission of the mother whenever possible

⁸⁰ R.S.N.S. 1989, c. 215, as am. 1991, c. 13; see also *Human Tissue Act*, R.S.N.B. 1973, c. H-12, as am. S.N.S. 1984, c. 25; S.N.S. 1986, c. 44; S.N.S. 1990, c. 61; S.N.S. 1992, c. 52, and the *Human Tissue Gift Act*, R.S.O. 1990, c. H-20.

⁸¹ See *Human Tissue Act*, S.M. 1987-88, c. 39, s. 1 and *Human Tissue Donation Act*, R.S.P.E.I. 1992, c. 34, s. 1(g).

⁸² See N.S. Reg. 16/79 enacted pursuant to *Hospitals Act*, R.S.N.S. 1989, c. 208, s. 17, and N.B. Reg. 92-84, s. 45, enacted pursuant to *Hospital Act*, S.N.B. 1992, c. H-6.1, as am. S.N.B. 1992, c. 52.

⁸³ *Supra* note 14 at 138.

⁸⁴ *Supra* note 10 at 993.

and to provincial human-tissue-gift legislation and hospital regulations.⁸⁵

This might suggest that the procurement and use of tissue obtained from a dead, aborted fetus is acceptable according to Canadian policy standards.

iv. Institutional Policy Guidelines

At present, in the absence of any mandated consent processes, each individual institution involved in fetal tissue transplantation must assess for itself the ethical issues relevant to the procedures, and monitor itself accordingly. Any need for obtaining informed consent to the procurement and use of fetal tissue will be determined by the internal ethics committee's views on the status of the dead fetus. However, by convention, these institutions generally look to the MRC *Guidelines* for guidance. There are no other published guidelines for human biomedical research in Canada; thus, the use of the MRC *Guidelines* does not necessarily reflect a voluntary decision on the part of these institutions.⁸⁶

To date, it appears that the Victoria General Hospital is the only hospital in Canada which has approved an internal policy relating to the procurement and use of fetal tissue.⁸⁷ According to Dr. J. V. Jones,⁸⁸ former Chair of the Victoria General Research Review Committee, a woman must provide voluntary, informed consent before she can obtain an abortion. *After* her consent has been given to the abortion procedure, the pregnant woman is then asked if she can be approached by someone responsible for obtaining consent with respect to the procurement of fetal tissue. If the woman agrees, she is approached by that individual (who is not one of the researchers or physicians involved in the transplant procedure), and asked if she will consent to the use of the aborted fetal tissue in a transplantation experiment. The woman is made aware of the details of the transplantation procedure, and is in no way pressured to give her consent. If the woman consents to the procurement of the fetal tissue, she is then asked to sign a second, separate consent form, which has been approved by the Research Review Committee. Thus, the cornerstone of

⁸⁵ Medical Research Council of Canada, *Guidelines on Research Involving Human Subjects* (Ottawa: Minister of Supply and Services Canada, 1987) at 32.

⁸⁶ *Supra* note 14 at 133.

⁸⁷ *Supra* note 14 at 133.

⁸⁸ Personal communication, (22 April 1994).

the Victoria General Hospital procurement process is the free and informed consent of the pregnant woman, obtained subsequent to, and separate from, the consent to an abortion.

2. Adaptability of Existing Regulatory Controls

The present human tissue gift legislation balances the rights of an individual over his or her body with the potential benefit to others conferred by either *inter vivos* or post-mortem donations of organs and tissues. Although fetal tissue is not specifically included in this legislative scheme, it could be argued that, by analogy, the intentions of the legislation must be deemed to apply to fetal tissue transplantation. This interpretation would at least ensure that some measure of consent to the use of fetal tissue is obtained from a pregnant woman who is about to undergo an abortion.

However, the distinction between *inter vivos* and post-mortem donations becomes confused when applied to the situation of a living mother donating tissue obtained from a dead fetus. If the procurement of tissue from a dead fetus is deemed to be a post-mortem donation, then the legislation allows persons other than the mother to consent to the use of the tissue. Yet, I have chosen to view the status of a dead fetus as being equivalent to that of a tissue specimen taken from the mother; therefore, only the mother should be able to provide consent to the procurement of fetal tissue. Can the donation therefore be considered an *inter vivos* gift? The answer to this question is not clear, and there is no indication in the legislation as to which type of donation would best accommodate the procurement of tissue from a dead fetus.

Even if human tissue gift legislation could be adapted for fetal tissue transplantation, there is no provision to protect against coercion of a pregnant woman, nor does the legislative scheme address any of the other unique and complicated issues presented by the use of fetal tissue. Furthermore, as D. K. Martin suggests, human tissue gift legislation applies only to persons;⁸⁹ since the Supreme Court of Canada and relevant case law have indicated that a fetus is not a person,⁹⁰ the legislation should not apply directly to the fetus, and might not apply to surrogate consent by the mother on the fetus' behalf. Finally, any modification of this legislation would require a considerable number

⁸⁹ *Supra* note 14 at 132–33.

⁹⁰ See for example, McConnell, *supra* note 40.

of alterations.⁹¹ Hence, the existing human tissue gift legislation is not adequate to meet the special regulatory requirements of this area of tissue procurement.

The existing regulations relating to disposal of abortuses are also not sufficiently adaptable to provide a comprehensive regulatory regime for the procurement of fetal tissue for transplantation. The regulations merely leave it up to the hospitals to dispose of the tissue according to the dictates of their internal policy guidelines. More specific legislative or regulatory directions which address issues such as informed consent to the use of fetal tissue, and which are cognizant of the potential exploitation of pregnant women and fetuses, are required.

According to the MRC *Guidelines*:

At this time, the legal status of embryos and fetuses is not well defined, nor is the social consensus. While issues of consent and autonomy may not therefore apply, clear ethical concerns arise from the unarguable fact that embryos and fetuses are human life forms.⁹²

This uncertainty would suggest that these *Guidelines* also do not provide an adequate response to the unique ethical questions raised by the concept of fetal tissue transplantation. Furthermore, the *Guidelines* are directed primarily at research on embryos and *in utero* fetuses. Hence, they do not contemplate the procurement of tissue from dead fetuses. In addition, because fetal tissue transplantation is not currently supported through public funding, the *Guidelines* do not strictly apply.⁹³ Clearly, there is a need in Canada, in the wake of increasing incursions into the realm of fetal tissue transplantations, to establish firm regulatory controls which can ensure that all parties to the procedure are properly protected.

3. Regulation in Other Jurisdictions

i. Australia

According to the report of the Australian Medical Research Ethics Committee, it is acceptable to use aborted fetal tissue for research or therapy, as long as the fetus does not attain a gestational age of 20

⁹¹ See for example, Morgan, *supra* note 6 at 297–301.

⁹² *Supra* note 85 at 32.

⁹³ *Supra* note 14 at 133.

weeks and does not exceed 400g in weight. Research protocols must be approved by a properly constituted ethics committee, and the abortion procedure must be completely separate from the tissue procurement process. Consent of the mother and, where practicable, the father, is required. The intending researcher is not permitted to approach the pregnant woman to solicit consent to the procurement of the aborted fetal tissue.⁹⁴

ii. Britain

Current British guidelines for fetal tissue research stipulate that the pregnant woman's consent to undergo an abortion must be kept separate from her consent to donate the resulting fetal tissue. No direct contact is allowed between the abortion clinics and the tissue researchers,⁹⁵ and there should be no financial reward for donating fetal tissue.⁹⁶

iii. Sweden

In Sweden, provision guidelines allow tissue to be taken only from dead fetuses. The pregnant woman must give her informed consent, and the decision to donate should not in any way affect the method or timing of abortion.⁹⁷

iv. The United States

In every state, the *Uniform Anatomical Gift Act* allows the donation of fetal tissue or organs provided that there is documented parental consent.⁹⁸ However, eight states have laws which prohibit the experimental use of dead fetal tissue obtained from induced abortions.⁹⁹ The U.S. House of Representatives has also recently passed Bill H.R. 2507 which requires, firstly, that a woman who has agreed to donate fetal tissue certify that she did not have an abortion with the intent to donate the tissue; and, secondly, that this certification be kept on file by researchers involved in fetal tissue research. These two require-

⁹⁴ J. Gunning, *Human IVF, Embryo Research, Fetal Tissue for Research and Treatment, and Abortion: International Information* (London: H.M.S.O., 1990) at 13.

⁹⁵ *Supra* note 1 at 3.

⁹⁶ *Supra* note 10 at 1012.

⁹⁷ *Ibid.*

⁹⁸ *Supra* note 94 at 44.

⁹⁹ See, for example, *Illinois Abortion Law of 1975*, Il. S.C. 510/12.1.

ments have been hotly contested, as they are viewed as an invasion of the woman's privacy, and a violation of her rights to autonomy and confidentiality.¹⁰⁰

4. Proposed Model for Regulatory Control

We are very conscious of the need to address the many ethical and social questions raised by fetal tissue use and to safeguard against the possible risks of coercion, commercialization, and the promotion of abortion.¹⁰¹

The serious ethical concerns raised by a discussion of fetal tissue transplantation indicate that some form of regulatory control of this procedure is needed. There are currently no directly applicable national guidelines or policy statements which sufficiently deal with the matter; nor is the existing legislation properly adaptable to meet the unique problems raised by fetal tissue transplantation. Hence, we cannot address all of the concerns raised by this issue by maintaining the status quo. It is possible to modify the existing human tissue gift legislation so that it can specifically include fetal tissue. However, the unique and complex ethical questions generated by a consideration of fetal tissue transplantation cannot be sufficiently addressed by such an amendment.

Therefore, I propose that a new statute be enacted to deal with all matters relating to embryos, fetuses, and reproduction (that is, those issues dealt with by the Royal Commission on New Reproductive Technologies). One section of this new statute would specifically address the use of aborted fetal tissue for medical purposes. Consequently, there would be a number of provisions expressly dealing with the issue of fetal tissue transplantation.

It is possible that such proposed legislation could be viewed as falling under either the federal or provincial legislative jurisdiction, as provided in sections 91 and 92 of the *Constitution*.¹⁰² The legislators might choose to tie the subject matter of the statute to the creation of crimes under the federal Government's jurisdiction over criminal law, in subsection 91(27) of the *Constitution*. Alternatively, the legislation could be framed so as to fall within the federal Government's residual

¹⁰⁰ W. Kearney, D. E. Vawter, & K. G. Gervais, "Fetal Tissue Research and the Misread Compromise" (1991) 21 *Hast. Cent. Rpt.* 7.

¹⁰¹ *Supra* note 10 at 990.

¹⁰² *Constitution Act, 1867* (U.K.), 30 & 31 *Vict.*, c. 3.

powers relating to peace, order and good government, in section 91 of the *Constitution*. Either approach would allow for the creation of a federal regulatory scheme relating to fetal tissue transplantation, similar to that favoured by the Royal Commission on New Reproductive Technologies.¹⁰³

A less controversial route is to frame the legislation in such a way as to ensure that it clearly falls within the provinces' jurisdiction over health, under the head of "property and civil rights" in subsection 92(13) of the *Constitution*. Such provincial legislation would focus on the protection of relevant rights and interests, as opposed to the creation of penal sanctions.

Specifically, the new legislation should set up restrictions which will protect all of the parties to the fetal tissue transplantation procedure. A prominent section on consent should delineate the essential requirements for a free and informed consent. As with the Victoria General Hospital consent process, the pregnant woman should not be approached for the purpose of procuring the dead fetus' tissue until after she has consented to have an abortion. This is also consistent with the consent processes in both Australia and Britain. This ensures that abortion management is clearly separated from the procurement of fetal tissue. Unlike the Australian consent process, however, only the consent of the mother should be required (although I offer no opinion as to whether or not the father should have the right to consent to the preceding abortion).

As with the Australian consent process, neither the physicians nor the researchers involved in the ensuing transplantation operation should be permitted to solicit from the pregnant woman any consent to tissue procurement; rather, the pregnant woman should be approached by a neutral party, so as to protect the woman from coercion. In addition, the pregnant woman should be prevented from designating the recipient of the fetal tissue, and the researchers should not be permitted to name the potential recipient of the tissue, if he or she is known. This, too, will help prevent coercion of the pregnant woman, and diminish any possibility of fetal tissue harvesting for friends and family members.

Bernard Dickens suggests that the prevention of tissue designation can be approached by either criminal or non-criminal sanctions against prospective donors, or indirectly by regulation of health pro-

¹⁰³ *Supra* note 10.

professionals or facilities.¹⁰⁴ I favour the latter as most pregnant women who elect to have abortions are in vulnerable positions. The pregnant woman therefore should not be punished when it is really those in positions of superiority, or those who owe her fiduciary obligations, who should be held responsible for coercing her into designating the recipient of her fetal tissue. Hence, no certification of ethical intent should be required, as in the proposed U.S. legislation.

The transplantation procedure should be explained to the pregnant woman so that her *voluntary* decision is also *informed*. However, there should not be any need to explain the possibility of additional risk to the woman, as such risk should be non-existent. Since consent to donate cannot be solicited until after the woman has consented to a particular abortion procedure, the researchers will be unable to request a different, and perhaps more risky, abortion procedure which might produce more medically-useful fetal tissue. Consequently, the researchers and physicians involved in the transplantation procedure must be content with the type of abortion to which the woman has previously consented. Future fetuses should be protected through a prohibition on the sale of fetal tissue and products made from fetal tissue. This will ensure that a bio-commerce in fetal tissue does not develop. As well, there should be a prohibition on payment to a pregnant woman in exchange for aborted fetal tissue. This can help prevent both the establishment of a market in fetal tissue and the coercion of pregnant women.

Finally, the new legislation should include a provision directed at the recipient of the fetal tissue. The transplantation procedure should not be allowed to proceed until the treatment is fully explained to the recipient, and all material risks are disclosed. As well, there must be standards which ensure that a recipient is not coerced into receiving a fetal tissue transplant. The transplant operation therefore should not occur until both the pregnant woman, and the recipient of the fetal tissue, have given free and informed consent.

The relevant part of this proposed legislation might take the following form:¹⁰⁵

¹⁰⁴ B. M. Dickens, "Legal Issues in Embryo and Fetal Tissue Research and Therapy" in *Research Volumes of the Royal Commission on New Reproductive Technologies* (Ottawa, 1992) 43.

¹⁰⁵ For another variation, see *supra* note 48.

An Act Respecting Abortion, Embryo Research, and the Use of
Fetal Tissue for Research and Treatment

....

Part X

*Procurement and Use of Tissue from Therapeutically-Aborted
Fetuses*

Consent by Donor

1. (1) Any legally competent woman undergoing a therapeutic abortion may donate the aborted fetus or its tissues. Hereafter, any such legally competent woman who donates her aborted fetus shall be referred to as a "donor."
- (2) Informed consent, in writing, is required from a donor before her aborted fetus, or its tissues, may be procured and used for medical research or treatment.
- (3) Consent to the procurement and use of an aborted fetus, or its tissues, may not be solicited from a donor until after she has given free and informed consent, in writing, to the abortion procedure.
- (4) No person engaged in carrying out a transplantation procedure under Part X of this Act shall be permitted to solicit consent to the procurement of an aborted fetus or its tissues.

Prohibition Against Designation

2. (1) No person shall request a donor to specifically designate the recipient of tissue donated under Part X of this Act.
- (2) No donor shall designate the recipient of tissue donated under Part X of this Act.
- (3) The name of the recipient of tissue donated under Part X of this Act shall not be disclosed to the donor.

Prohibition Against Commercial Exchange or Payment

3. (1) It shall be unlawful to knowingly engage in any sale or commercial exchange of aborted fetuses or fetal tissue or products made from fetal tissue.

(2) It shall be unlawful to provide payment to any donor in exchange for the procurement and use of the aborted fetus or its tissues.

Consent of the Recipient

4. No transplantation procedure under Part X of this Act shall proceed until the informed consent, in writing, of the recipient undergoing such transplantation procedure has been obtained.

IV. CONCLUSION

Legislation cannot resolve all of the problems in today's complex society. However, the unique ethical concerns raised by an analysis of the issues relating to fetal tissue transplantation deserve the special attention of legislators. New legislation should be drafted to regulate the procurement and use of tissue obtained from dead, aborted fetuses. This new regulatory regime can fill the lacunae which currently exist in the law. The new enactment should address previously overlooked issues, such as the requirement for voluntary, informed consent from both the donating mother and the tissue recipient, avoidance of coercion, and prohibitions on the commodification and commercialization of fetuses and fetal tissue. It is hoped that as the medical technology in this field of research continues to advance and improve, and that the regulation of such research may similarly advance and improve, thereby providing legal protection to all who might be affected by this contentious technological procedure.